

# Randomized Prospective Study of Self-Management Training With Newly Diagnosed Diabetic Children

Alan M. Delamater, PhD  
Jeanne Bubb, MSW  
Susan G. Davis, MSN  
Jeffrey A. Smith, PhD  
Lois Schmidt, RD  
Neil H. White, MD  
Julio V. Santiago, MD

This study was designed to evaluate the effects of a self-management training (SMT) program on metabolic control of children with insulin-dependent diabetes mellitus (IDDM) in the first 2 yr after diagnosis. After standard in-hospital diabetes education, 36 children (mean age 9.3 yr, range 3–16 yr) were randomized to conventional follow-up, conventional and supportive counseling (SC), or conventional and SMT, which emphasized use of data obtained from self-monitoring of blood glucose. SC and SMT interventions consisted of seven outpatient sessions with a medical social worker during the first 4 mo after diagnosis and booster sessions at 6 and 12 mo postdiagnosis. Groups were similar with respect to age, sex, body mass index, socioeconomic status, C-peptide, and severity of illness at diagnosis. Metabolic control, measured quarterly by glycosylated hemoglobin (HbA<sub>1c</sub>), improved substantially in all three treatment groups during the first 6 mo. SMT patients had significantly lower HbA<sub>1c</sub> levels than conventional patients at 1 yr ( $P < 0.01$ ) and 2 yr ( $P < 0.05$ ) postdiagnosis. SMT patients also had lower HbA<sub>1c</sub> levels than SC patients, but this did not reach statistical significance. The lower HbA<sub>1c</sub> levels of SMT patients were not explained by severity of illness at diagnosis, or insulin dose, body mass index, and C-peptide levels at 2 yr. These results suggest that an SMT program during the first few months after diagnosis helps avoid the deterioration in metabolic control often seen in children

with IDDM between 6 and 24 mo after diagnosis. *Diabetes Care* 13:492–98, 1990

It is generally acknowledged that the diagnosis of insulin-dependent diabetes mellitus (IDDM) in children imposes considerable stress on young patients and their families (1–3). Not only must patients and families begin to adjust to life with a chronic illness, they must also learn a substantial amount of new information and become proficient with the skills necessary for optimal diabetes management. Typically, education and training begin in several sessions during hospitalization at the time of diagnosis. This process plays an important role in the initial management of diabetes, but it occurs during a time of great stress, which is not the best time for learning and retaining all that is required for effective diabetes management.

Ideally, patients would be taught to manage diabetes by mastering self-management information and skills over time in the context of a collaborative relationship with the health-care team. Self-management assumes that patients and/or families actively use data from self-monitoring of blood glucose (SMBG) for initiating behavioral changes regarding eating, exercise, and insulin use. In practice, however, many patients and families assume more passive roles and do not achieve the degree of skill, confidence, and autonomy required for effective self-management. Although initially promising, routine use of SMBG in children has been somewhat disappointing; technical-skill deficits and adherence problems are common, and SMBG alone has not been associated with improved metabolic control (4–6). Given that education alone (i.e., presentation of information)

Glucose 1 mM = 18 mg/dl

From Wayne State University, Detroit, and the University of Michigan, Ann Arbor, Michigan; the Edward Mallinckrodt Department of Pediatrics, Washington University School of Medicine, St. Louis, Missouri; and the University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania.

Address correspondence and reprint requests to Alan M. Delamater, PhD, Department of Psychology, Wayne State University, 71 West Warren Avenue, Detroit, MI 48202.

Received for publication 21 August 1989 and accepted in revised form 29 November 1989.

is not sufficient to ensure desired behavioral changes and improved metabolic control, it is reasonable to assume that most patients must be taught to use SMBG for day-to-day self-management and that this process must be encouraged and reinforced by the health-care team over time (7,8).

Few controlled studies evaluating the effectiveness of specific education and treatment approaches for newly diagnosed diabetic children have been reported. Available results suggest that supportive interventions emphasizing disease management skills may lead to improved adjustment (9) and metabolic control (V.A. Nerup, D.F. Larsen, unpublished observations). The purpose of this study was to evaluate the effects of a family-based self-management training (SMT) program, which emphasized use of SMBG and was conducted during the first 6 mo after diagnosis, on metabolic control in the first 2 yr. A randomized prospective design was used to test the hypothesis that an SMT program initiated early in the disease course would prevent the expected worsening of metabolic control at the end of the honeymoon period. To control for the effects of the increased health-care team contact experienced by patients in the SMT group, a control treatment providing supportive counseling (SC) was used. We predicted that patients receiving SMT would have better metabolic control during a 2-yr follow-up than patients receiving conventional outpatient procedures. We also expected that SMT patients would have better metabolic control than SC patients.

## RESEARCH DESIGN AND METHODS

All children between 3 and 16 yr of age with newly diagnosed IDDM presenting at Children's Hospital, Washington University Medical Center in St. Louis, between September 1983 and December 1985 were asked to participate. Of 57 newly diagnosed diabetic patients admitted during the recruitment period, 40 met our criteria, and of these, 36 agreed to participate. Subjects were excluded if they had other chronic disease, psychiatric disorder, or lived >90 miles from the hospital. Five patients were too young, 8 lived too far away, 1 had a psychiatric disorder, and 3 were to be followed elsewhere.

All children were hospitalized at the time of initial diagnosis. While still in the hospital, the child and his/her parents were told about the study, and informed consent was obtained. All patients received the same standard in-hospital diabetes education provided by the same nurse educator, including instructions and endorsement of SMBG. In addition, they met with a dietitian to learn about food exchanges and to receive a prescribed meal plan. The education and training took place in several sessions over ~5 days of hospitalization.

Baseline assessment data included an interview with the parents to obtain demographic information and risk-factor analysis based on socioeconomic status (SES) and

disease severity, previously shown to be predictive of metabolic control problems in newly diagnosed children (10). SES was determined by the Hollingshead Four-Factor Index of Social Position (11). Illness severity ratings were made based on serum bicarbonate levels at diagnosis. Inclusion in the severe-moderate group required serum bicarbonate levels to be  $\leq 20$  meq/L, and inclusion in the mild group required serum bicarbonate  $> 20$  meq/L. For this study, patients were considered high risk with either low SES or moderate-severe illness at the time of diagnosis. Other baseline assessments included glycosylated hemoglobin (HbA<sub>1c</sub>) and basal and Sustacal-stimulated C-peptide tests. Initial C-peptide was determined several days after resolution of ketoacidosis; C-peptide tests were also conducted 1 and 2 yr postdiagnosis. Throughout the course of the study, HbA<sub>1c</sub> was obtained quarterly.

After inpatient education was completed and just before discharge from the hospital, patients were stratified by age, sex, and risk status and then randomized into one of three treatment groups: conventional, conventional and SC, or conventional and SMT. Baseline patient demographic characteristics for each of the three treatment groups are shown in Table 1. Baseline clinical measurements for each treatment group are shown in Table 2. Statistical analyses revealed no differences between the groups on any of the baseline measurements.

**Conventional treatment.** After discharge from the hospital, all patients followed standard hospital procedures that consisted of regular outpatient contact with the health-care team. In the first few weeks after discharge, telephone contacts were made as needed. Patients were seen at the outpatient clinic 1 and 3 mo after discharge and every 3 mo thereafter. Patients were prescribed two daily insulin injections and 2–4 daily blood glucose measurements. All patients were provided with Chem-strip bG test strips during the study and received strips free of charge as needed at outpatient visits. Individualized meal plans were modified as needed during outpatient clinic appointments. Patients were managed throughout the study by the same group of physicians and dietitians who were unaware of group assignments.

**SC.** In addition to conventional treatment, patients randomized to SC were seen with their parents for seven sessions during the first 4 mo (wk 1, 2, 5, 7, 9, 12, and 16), with additional sessions at 6 and 12 mo postdiagnosis. The therapist, a medical social worker with expertise in diabetes, focused on psychosocial adjustment issues, coping with the regimen, and family involvement in a supportive manner. SMBG was encouraged without any emphasis placed on self-management techniques. Patients were encouraged to keep accurate SMBG records so the health-care team could plan the best treatment for them. This group served as an attention-placebo group to control for the effects of therapist contact in the SMT group.

**SMT.** In addition to conventional treatment, SMT patients and parents participated in seven sessions held in the 4 mo after discharge from the hospital on the same

**TABLE 1**  
Baseline demographic characteristics for treatment groups

	Treatment groups (n = 36)			F	$\chi^2$
	Conventional	Supportive	Self-management		
Age (yr)	9.8 $\pm$ 2.6	8.6 $\pm$ 4.1	9.3 $\pm$ 3.9	0.37	
Male (%)	50	50	58		0.22
White (%)	92	75	92		1.85
Social stratum*	3.4 $\pm$ 1.1	2.7 $\pm$ 1.2	3.7 $\pm$ 1.1	2.90	
Levels (%)					
1	0	16.7	0		
2-4	75	75	83.3		5.07
5	25	8.3	16.7		

Values are means  $\pm$  SD.

\*Social stratum was determined by Hollingshead Four-Factor Index of Social Position (11), categorized by levels 1-5. All statistical comparisons were nonsignificant.

schedule as the SC group. The emphasis during these sessions was on SMBG technique, reinforcement of accurate monitoring and recording, and use of SMBG data for understanding blood glucose fluctuations and making appropriate behavioral changes. Home exercises were prescribed to demonstrate common causes of blood glucose fluctuations. In these exercises patients investigated the effects on blood glucose of various foods, physical exercise, and modifying injection-meal intervals based on preprandial blood glucose. The goal was to develop and reinforce problem-solving strategies and integrate data from SMBG into their daily life to guide decisions concerning self-management. Parents were instructed in the use of contingent praise for appropriate regimen behaviors by their child. Additional contact for review and reinforcement of self-management strategies occurred at

6 and 12 mo postdiagnosis. A session-by-session description of SMT topics and assignments is provided in Appendix 1. SMT and SC interventions were conducted by the same therapist.

**Measures.** The primary dependent measure in this study was HbA<sub>1c</sub>, an accepted objective measure of long-term metabolic control. HbA<sub>1c</sub> concentration was determined from a saline-incubated blood sample with the mini-column method (Isolab, Akron, OH). The assay was performed under the supervision of the Diabetes Research and Training Center of Washington University. The normal nondiabetic mean  $\pm$  SD for this assay was 6.0  $\pm$  0.6%.

Residual pancreatic  $\beta$ -cell activity was measured by C-peptide that was obtained under basal and Sustacal-stimulated conditions. Patients provided a blood sample

**TABLE 2**  
Clinical characteristics of treatment groups

	Treatment groups			F
	Conventional	Supportive	Self-management	
Baseline				
Serum bicarbonate (meq/L)	18.9 $\pm$ 6.7	18.6 $\pm$ 4.9	15.9 $\pm$ 8.5	0.63
Blood glucose (mg/dl)	518 $\pm$ 135	428 $\pm$ 152	607 $\pm$ 274	2.22
HbA <sub>1c</sub> (%)	12.3 $\pm$ 2.5	11.1 $\pm$ 2.4	10.4 $\pm$ 3.1	1.61
C-peptide (ng/ml)	0.5 $\pm$ 0.3	0.8 $\pm$ 0.6	0.3 $\pm$ 0.2	2.60
Body mass index	31.2 $\pm$ 9.7	27.6 $\pm$ 8.3	32.9 $\pm$ 15.1	0.67
One year				
HbA <sub>1c</sub> (%)	9.3 $\pm$ 1.7	8.5 $\pm$ 1.5	8.1 $\pm$ 1.2	3.59*
C-peptide (ng/ml)	1.1 $\pm$ 1.7	1.1 $\pm$ 1.3	0.5 $\pm$ 0.4	0.86
Two years				
HbA <sub>1c</sub> (%)	9.8 $\pm$ 2.4	9.1 $\pm$ 1.7	8.2 $\pm$ 1.5	2.61†
C-peptide (ng/ml)	0.8 $\pm$ 1.4	1.0 $\pm$ 1.4	0.5 $\pm$ 0.5	0.39
Insulin (U/kg)	1.4 $\pm$ 0.2	1.3 $\pm$ 0.4	1.4 $\pm$ 0.5	0.44
Body mass index	46.0 $\pm$ 15.0	36.4 $\pm$ 16.4	43.7 $\pm$ 18.5	1.02

Values are means  $\pm$  SD. n = 9 self-management training (SMT) patients for baseline HbA<sub>1c</sub> due to missing data on 3 points.

\*P < 0.04 for omnibus F; planned comparison SMT < C, P < 0.01.

†P < 0.09 for omnibus F; planned comparison SMT < C, P < 0.05.

in the morning before insulin administration and breakfast (basal) and then consumed a test meal of Sustacal (Mead Johnson) within 10 min of the blood sample. The amount ingested was equal to 20% of the total daily calorie requirement, with a maximum of 360 calories. Ninety minutes later another blood sample was obtained after which patients administered their usual insulin dose. All samples were frozen at  $-20^{\circ}\text{C}$  and measured subsequently in the same radioimmunoassay. The assay was performed in the Radioimmunoassay Core Facility of the Diabetes Research and Training Center with the techniques of Heding (12) and antibody obtained from Novo Research Laboratories (Copenhagen).

Patients were instructed to keep logbooks of SMBG results throughout the study. The logbooks were copied at each clinic visit, and from these we obtained the number of blood glucose tests conducted per month. For study purposes we sampled 1-mo records at 6-, 12-, 18-, and 24-mo visits. Patients were also instructed to keep records of all food intake for 1 wk before their clinic visits at 1 and 2 yr postdiagnosis. The last 3 days of these records were coded by a dietitian who was blind to group assignments, and dietary deviations were determined according to procedures described by Christensen et al. (13) yielding a percent total deviation score. In addition, patients were instructed to record the time intervals between injections and meals for 1 wk before the 1- and 2-yr postdiagnosis appointments. Measurements of injection-meal timing deviations were obtained from these records by using records of preprandial blood glucose levels. All patients had previously been taught to vary the injection-meal interval according to the following: blood glucose  $<70$  mg/dl, eat within 15 min of injection; blood glucose 70–80 mg/dl, eat in 30 min; blood glucose 180–240 mg/dl, eat in 45 min; blood glucose  $>240$  mg/dl, eat in 60 min. With this criteria, the mean absolute number of minutes each patient deviated from this ideal was calculated for each week.

Patient hospital charts were reviewed to obtain measures of blood glucose and serum bicarbonate at hospital admission for diagnosis and frequency of severe hypoglycemia and hospital admission for ketoacidosis throughout the study. Only hypoglycemic episodes resulting in loss of consciousness or seizures and/or requiring oxygen or intravenous administration were counted. Ketoacidosis was defined as an episode of serum bicarbonate levels  $<15$  meq/L associated with ketonuria, hyperglycemia, and the need for hospital or emer-

gency department care. We also obtained from the charts measures of body mass index at diagnosis and 2 yr postdiagnosis and insulin dose at 2 yr postdiagnosis.

**Statistical methods.** One-way analyses of variance (ANOVA) or  $\chi^2$ -tests were used to compare the groups at baseline on measures of demographic characteristics and clinical variables. Correlational analyses were performed to determine relationships among relevant patient variables and 2-yr HbA<sub>1c</sub>. Primary analyses of the study used analysis of covariance (ANCOVA) on 1- and 2-yr HbA<sub>1c</sub> with 1- and 2-yr stimulated C-peptide as the respective covariates, due to their significant correlations with HbA<sub>1c</sub>. A repeated-measures ANOVA with HbA<sub>1c</sub> data from 3 to 24 mo postdiagnosis was conducted to determine group differences in HbA<sub>1c</sub> over time. This analysis blocked the data into 4 units by taking the mean of months 3 and 6, 9 and 12, 15 and 18, and 21 and 24. Frequency of severe hypoglycemia and diabetic ketoacidosis was subjected to  $\chi^2$ -analyses. Group differences on regimen adherence variables were evaluated with ANOVAs.

## RESULTS

As shown in Tables 1 and 2, analyses indicated that the groups were not significantly different on measures of baseline demographic and clinical characteristics. Mean stimulated C-peptide at 1 and 2 yr postdiagnosis are shown for treatment groups in Table 2. There were no differences between the groups as indicated by ANOVAs. One-year stimulated C-peptide was significantly correlated with 1-yr HbA<sub>1c</sub> ( $r = -0.38$ ,  $P < 0.02$ ). An ANCOVA conducted on 1-yr HbA<sub>1c</sub> revealed a significant treatment group effect ( $F[2,30] = 3.59$ ,  $P < 0.04$ ). The planned comparison of SMT to conventional patients showed SMT patients to have lower HbA<sub>1c</sub> levels after controlling for C-peptide ( $F[1,21] = 7.53$ ,  $P < 0.01$ ).

As expected, correlational analyses revealed a significant relationship between 2-yr HbA<sub>1c</sub> and 2-yr stimulated C-peptide ( $r = -0.32$ ,  $P < 0.03$ ). Age, SES, baseline C-peptide and HbA<sub>1c</sub>, and 2-yr body mass index and insulin dose were unrelated to 2-yr HbA<sub>1c</sub>, as shown in Table 3. Two-year HbA<sub>1c</sub> data were missing for one patient in the SMT group whose family moved out of state after the 1st yr of the study; all other 2-yr HbA<sub>1c</sub> data were obtained.

**TABLE 3**  
Relationship of patient demographic and medical characteristics with 2-yr HbA<sub>1c</sub>

	Baseline				2 yr		
	Age	SES	HbA <sub>1c</sub>	C-peptide	C-peptide	Insulin dose	BMI
Two-year HbA <sub>1c</sub>	-0.14	-0.20	0.16	-0.07	-0.32*	-0.19	-0.09

Values are Pearson product-moment correlation coefficients. BMI, body mass index; SES, socioeconomic status.

\* $P < 0.03$ .

An ANCOVA conducted on 2-yr HbA<sub>1c</sub> indicated a marginally significant treatment group effect ( $F[2,31] = 2.60$ ,  $P < 0.09$ ). However, the planned comparison of SMT to conventional patients was significant ( $F[1,20] = 4.10$ ,  $P < 0.05$ ), with lower HbA<sub>1c</sub> levels observed in SMT patients. The 1- and 2-yr HbA<sub>1c</sub> levels of SC patients were intermediate to and not significantly different from SMT or conventional patients. There were no differences among groups in insulin dose and body mass index at 2 yr (Table 2).

Figure 1 shows HbA<sub>1c</sub> data for treatment groups from diagnosis to 24 mo postdiagnosis at 3-mo intervals. Repeated-measures ANOVA revealed a significant temporal effect ( $F[3,28] = 10.94$ ,  $P < 0.001$ ) with increasing HbA<sub>1c</sub> over time. The treatment groups-by-time interaction effect was not significant ( $F[6,54] = 1.82$ ,  $P < 0.11$ ), but SMT patients maintained lower HbA<sub>1c</sub> levels than SC or conventional patients throughout the study after the first 6 mo (Fig. 1).

Metabolic control was also evaluated by comparing the frequencies of severe hypoglycemia or diabetic ketoacidosis. There were eight occurrences of severe hypoglycemia: five in the SMT group, two in SC, and one in the conventional group. In the SMT group four of five episodes occurred in two children <6 yr of age who had two episodes each. Overall, five of eight episodes (63%) occurred in children ≤5 yr of age. There were only two occurrences of diabetic ketoacidosis postdiagnosis: one patient was in the SMT group and the other in the SC group. The  $\chi^2$ -analyses indicated there were no group differences in hypoglycemia or diabetic ketoacidosis.

Regimen adherence on selected variables was evaluated by analysis of patient self-monitored records. Patient SMBG logbooks for the month preceding the 6-, 12-, 18-, and 24-mo postdiagnosis visits were sampled. Records were obtained from 32 patients (11 SMT, 10 SC, 11 conventional) at 6 mo, 34 (11 SMT, 11 SC, 12 conventional) at 12 mo, 30 (10 SMT, 9 SC, 11 conven-

tional) at 18 mo, and 33 (10 SMT, 11 SC, 12 conventional) at 24 mo. There were no differences between the groups in number of patients with missing records. The number of blood glucose tests conducted for each month sampled was evaluated with ANOVA. There were no significant effects noted, indicating similar frequency of recorded SMBG among treatment groups. Repeated-measures ANOVA revealed a similar pattern over time, as indicated by a nonsignificant treatment groups-by-time interaction. The mean  $\pm$  SD number of blood glucose tests for the sample for months 6, 12, 18, and 24 were  $74.1 \pm 23.9$ ,  $73.5 \pm 22.4$ ,  $72.9 \pm 20.0$ , and  $66.2 \pm 25.1$ , respectively.

One-week records of injection-meal intervals were obtained from 26 patients (10 in SMT, 6 in SC, and 10 in conventional) at 1 yr postdiagnosis and 22 patients (7 in SMT, 7 in SC, and 8 in conventional) at 2 yr postdiagnosis. Injection-meal timing deviations at 1 and 2 yr postdiagnosis were evaluated in separate ANOVAs. There were no differences among treatment groups ( $P > 0.30$ ). Mean  $\pm$  SD timing deviations for the sample were  $14.2 \pm 7.4$  min at 1 yr postdiagnosis and  $13.8 \pm 7.8$  min at 2 yr postdiagnosis.

Dietary records were obtained from 31 patients (9 in SMT, 10 in SC, and 12 conventional) at 1 yr postdiagnosis and 29 patients (8 SMT, 10 SC, and 11 conventional) at 2 yr postdiagnosis. Dietary adherence was similarly evaluated with ANOVAs conducted on 3-day samples at 1 and 2 yr. These results revealed a significant treatment group effect at 1 yr ( $F[2,28] = 3.52$ ,  $P < 0.04$ ). Post hoc Duncan tests showed significantly ( $P < 0.05$ ) fewer dietary deviations in SMT ( $28.1 \pm 12.3\%$ ) compared with conventional patients ( $42.9 \pm 13.2\%$ ); SC patients ( $38.4 \pm 12.6\%$ ) were not different from either group. There were no differences among treatment groups at 2 yr postdiagnosis; mean  $\pm$  SD for the sample was  $40.0 \pm 15.0\%$ .

## DISCUSSION

Results of this randomized prospective study demonstrate that patients who participated in a seven-session family-based SMT program conducted during the first 4 mo after diagnosis had significantly better metabolic control after 1 and 2 yr of diabetes than patients treated with conventional outpatient procedures. Measurements of HbA<sub>1c</sub> at 1 and 2 yr postdiagnosis were significantly lower in SMT compared with conventional patients (mean difference of 1.6% at 2 yr) after accounting for the effects of residual  $\beta$ -cell activity. Although there were no significant differences in C-peptide levels among treatment groups at any time, the lowest levels were observed for SMT patients. Therefore, the lower HbA<sub>1c</sub> levels of patients in the SMT group cannot be accounted for by greater  $\beta$ -cell function. The improved metabolic control of SMT patients also was not due to differences in insulin dose and body mass

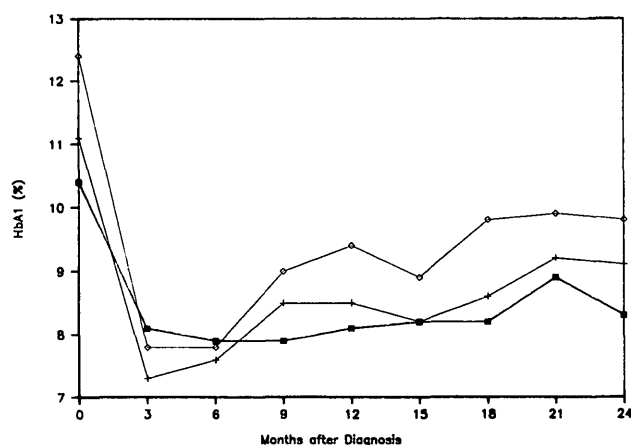


FIG. 1. Mean HbA<sub>1c</sub> levels of treatment group during first 2 yr. ◇, Standard; +, supportive; ■, self-management.

index, which were similar for all three treatment groups at 2 yr.

Patients in the three treatment groups were equated on all demographic and clinical measures due to the stratified randomization procedure used. Furthermore, the initial HbA<sub>1c</sub> measure was not significantly different among groups nor was it significantly correlated with 2-yr HbA<sub>1c</sub>. Thus, the improved metabolic control of SMT patients relative to patients treated conventionally cannot be accounted for by demographic or initial clinical characteristics, C-peptide levels, or body mass index and insulin dose.

What other factors could explain the observed effect? We attempted to measure several aspects of regimen adherence that could be associated with improved metabolic control. Unfortunately, not all patients completed all procedures for reliable measurement of SMBG frequency, dietary deviations, and injection-meal timing deviations. However, there were no systematic differences between the groups in terms of missing data on these measures. Analyses of available patient records indicated that the treatment groups differed only on dietary deviations at 1 yr postdiagnosis with SMT patients deviating significantly less than conventional patients. Overall, SMT patients had fewer dietary and injection-meal timing deviations than SC and conventional patients. It is possible that this trend may have been more significant than it would appear on the basis of these analyses, which had little statistical power given the small sample sizes attained on these measures.

The overall levels of nonadherence for dietary and injection-meal timing deviations were striking: by 2 yr, mean dietary deviations were 40% and injection-meal timing deviations were 14 min. These observations indicate that educational programs for newly diagnosed children are needed which focus on these regimen behaviors. Study patients reported performing frequent SMBG, an average of ~2.5/day. This alone is not surprising, given that patients were all volunteers in a research study that provided them with blood glucose testing strips free of charge. However, simply performing SMBG frequently was not sufficient to produce improvements in metabolic control.

Patients treated with SC had HbA<sub>1c</sub> levels that fell between SMT and conventional patients. Although there was not a statistically significant difference between SMT and SC patients, the HbA<sub>1c</sub> mean difference of ~1% at 2 yr postdiagnosis may be clinically significant. For this difference to have been statistically significant, substantially more study patients would have been required (50 patients/group at power of 0.80). Thus, this study did not have sufficient power to detect potentially significant clinical differences between SMT and SC treatment, originally designed as an attention-placebo condition to control for the effects of additional therapist contact time. Results indicate that, although supportive intervention may confer some benefits of its own in the early stages of diabetes, it is not sufficient to improve metabolic con-

trol because SC patients did not have significantly lower HbA<sub>1c</sub> levels than patients treated conventionally.

There were several unique features of the SMT used in this program: it emphasized use of SMBG, had an experiential basis (i.e., required families to perform SMBG homework assignments), was family based, incorporated behavioral principles, was conducted by a medical social worker, and it began soon after diagnosis. The emphasis on training and reinforcing active use of SMBG for problem solving and self-management is important because, although routinely prescribed, it is clear that children do not typically use SMBG for self-management (6). A recent controlled intervention study showed that training young patients in a group format to use SMBG for self-management prevented the expected worsening of metabolic control during early adolescence (14). Our results provide additional evidence that patients profit from being taught to use SMBG data and, furthermore, that such training can occur soon after diagnosis to prevent the expected deterioration of metabolic control after the honeymoon period ends during the first 2 yr of diabetes.

If self-management techniques can be enhanced early in the course of diabetes with a brief and inexpensive outpatient program, then the risk of long-term problems and worsening metabolic control may also be decreased. The honeymoon period would appear to be an optimal time for prevention-oriented training in adaptive self-management practices rather than a time for patients and families to develop inappropriate self-care habits that may put them at risk for later adherence and metabolic control problems.

In conclusion, results of this study indicate that early family based SMT may prevent the expected worsening of metabolic control in young patients with diabetes by the end of the honeymoon period. Based on these results, we suggest that education and training in SMBG-based self-management techniques be conducted in outpatient follow-up sessions within the first few months after diagnosis. Further studies are needed to determine whether the results obtained in this study can be replicated in other settings with newly diagnosed patients as well as those with established diabetes.

## ACKNOWLEDGMENTS

This research was supported by a grant from the Diabetes Research and Training Center (KD-20579), Washington University Medical Center, and by Public Health Service Research Grant RR-36 from the General Clinical Research Center Branch, Division of Research Facilities and Resources, Bethesda, Maryland. Boehringer Mannheim, Indianapolis, Indiana, generously provided all Chemstrips used by participants during the course of the study.

This research was presented at the 48th annual meeting of the American Diabetes Association, New Orleans, Louisiana, 11–14 June 1988.

## APPENDIX 1

## Description of self-management training program

Sessions	Topics	Assignments
1 (wk 1)	Blood glucose vs. urine testing, high/low blood glucose symptoms, ideal blood glucose range	Compare blood glucose/urine results, test blood glucose when feeling funny
2 (wk 2)	Effects of food on blood glucose, effects of injection-meal timing on postprandial blood glucose	Test blood glucose before and after snacks, compare blood glucose when waiting vs. not waiting between injection and meal
3 (wk 5)	Impact of physical exercise on blood glucose, insulin action, and dose adjustment	Test blood glucose before and 1 and 2 h after physical exercise
4 and 5 (wk 7 and 9)	Apply information from blood glucose records and assignments to daily life with problem-solving process	With problem-solving guide, record behavioral responses to out-of-range blood glucose levels
6 and 7 (wk 12 and 16)	Emphasize problem-solving process, question blood glucose fluctuations, and plan corrective strategies	Continue recording management decisions with problem-solving guide
Boosters sessions (mo 6 and 12 postdiagnosis)	Review and reinforce the self-management process	

## REFERENCES

- Geist RA: Onset of chronic illness in children and adolescents. *Am J Orthopsychiatry* 49:4–23, 1979
- Tarnow J, Tomlinson N: Juvenile diabetes: impact on the child and family. *Psychosomatics* 19:487–91, 1978
- Wishner WJ, O'Brien MD: Diabetes and the family. *Med Clin North Am* 62:849–56, 1978
- Daneman D, Siminerio L, Transue D, Betschart J, Drash A, Becker D: The role of self-monitoring of blood glucose in the routine management of children with insulin-dependent diabetes mellitus. *Diabetes Care* 8:1–4, 1985
- Wing RR, Lamparski DM, Zaslow S, Betschart J, Siminerio L, Becker D: Frequency and accuracy of self-monitoring of blood glucose in children: relationship to glycemic control. *Diabetes Care* 8:214–18, 1985
- Delamater AM, Davis SG, Bubbs J, Santiago JV, Smith JA, White NH: Self-monitoring of blood glucose by adolescents with diabetes: technical skills and utilization of data. *Diabetes Educ* 15:56–61, 1989
- Bloomgarden ZT, Karmally W, Metzger MJ, Brothers M, Nechemias C, Bookman J, Faierman D, Ginsberg-Fellner F, Rayfield E, Brown WV: Randomized, controlled trial of diabetic patient education: improved knowledge with out improved metabolic status. *Diabetes Care* 10:263–72, 1987
- Rettig BA, Shrauger DG, Recker RR, Gallagher TF, Wiltse H: A randomized study of the effects of a home diabetes education program. *Diabetes Care* 9:173–78, 1986
- Galatzer A, Amir S, Gil R, Karp M, Laron Z: Crisis intervention program in newly diagnosed diabetic children. *Diabetes Care* 5:414–19, 1982
- Hamman RF, Cook M, Keefer S, Young WF, Finch JL, Lezotte D, McLaren B, Orleans M, Klingensmith G, Chase HP: Medical care patterns at the onset of insulin-dependent diabetes mellitus: association with severity and subsequent complications. *Diabetes Care* 8 (Suppl. 1):94–100, 1985
- Hollingshead AB: *Four-Factor Index of Social Status*. New Haven, CT, Hollingshead, 1975
- Heding LG: Radioimmunological determination of human C-peptide in serum. *Diabetologia* 11:541–48, 1975
- Christensen NK, Terry RD, Wyatt S, Pichert JW, Lorenz RA: Quantitative assessment of dietary adherence in patients with insulin-dependent diabetes mellitus. *Diabetes Care* 6:245–50, 1983
- Anderson BJ, Wolf FM, Burkhart MT, Cornell RG, Bacon GE: Effects of peer-group intervention on metabolic control of adolescents with IDDM: randomized outpatient study. *Diabetes Care* 12:179–83, 1989